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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/214,836	10/04/99	FIGDOR	C VEOC.002.00U

EXAMINER	
RAWLINGS,S	
ART UNIT	**PAPER NUMBER**
1642	8

DATE MAILED: 11/21/00

HM12/1121
LAW OFFICE OF TRASK, BRITT, AND ROSSA
ATTN: MR. A.C. TURNER
P.O. BOX 2550
SALT LAKE CITY UT 84110

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/214,836	FIGDOR ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *Notice to Comply* .

DETAILED ACTION

1. Claims 1-19 are pending in the application and are currently under prosecution.

2. The Amendment filed February 19, 2000 (Paper No. 5) is acknowledged and has been entered. Claims 1-19 have been amended.

Sequence Rules

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.8821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons(s) set forth on the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer from the date of this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821 (g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Election/Restrictions

4. Restriction is required under 35 U.S.C. 121 and 372.

5. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group 1. Claims 1-2, 4, 6-7,11, 14-15, and 19 drawn to peptides comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue (claim 1), specifically claimed peptides comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein either an isoleucine, leucine, or valine residue replaces the amino acid residue at position 2 (claim 2), a specifically claimed peptide comprising SEQ ID NO:2 (claim 4), vaccines comprising said peptides or epitopes thereof (claims 6-7), a method of using said peptides in the specifically claimed process of isolating melanoma antigen reactive tumor infiltrating lymphocytes (claim 11), and a conjugate of a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue, and a detectable marker (claim 14), wherein said marker is a

radionuclide (claim 15), a kit comprising a conjugate of a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue, and a detectable marker, including a radionuclide (claim 19), classified in class 530, subclass 300, class 530, subclass 328, class 424, subclass 185.1, and class 435, subclass 810.

Group 2. Claim 3, drawn to peptides comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at position 2 within said sequence is replaced with either an isoleucine, leucine, or valine residue *and* wherein the amino acid residue at position 8 within said sequence is replaced with an alanine residue (claim 3), classified in class 530, subclass 300.

Group 3. Claims 5-7, drawn to nucleic acid molecules comprising a nucleotide sequence encoding a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue (claim 5), and vaccines comprising a nucleotide sequence encoding said peptides (claims 6-7), classified in class 536, subclass 23.1 and class 424, subclass 184.1.

Group 4. Claim 8, drawn to vaccines comprising an antigen presenting cell preloaded with a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue, classified in class 424 , subclass 93.1.

Group 5. Claim 9, drawn to vaccines comprising a T cell receptor against a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue, classified in class 530, subclass 350.

Group 6. Claim 9, drawn to vaccines comprising cells expressing a T cell receptor against a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue, classified in class 424 , subclass 93.1.

Group 7. Claims 12-13, drawn to tumor infiltrating lymphocytes that bind to a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue (claim 12), and a vaccine comprising a tumor infiltrating lymphocyte that binds to a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue (claim 13), classified in class 435, subclass 325 and class 424 , subclass 93.1.

Group 8. Claims 16 and 17, drawn to antibodies that are directed to a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue (claim 16), and vaccine comprising an antibody that is directed to a peptide

comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue (claim 17), classified in class 424, subclass 139.1.

Group 9. Claim 18, drawn to a method of monitoring progress of immunotherapy in a patient, classified in class 436, subclass 514.

Group 10. Claim 10, drawn to vaccines comprising peptides, or epitopes thereof, comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at position 2 *or* position 8 within said sequence is replaced with a substitute amino acid residue, and further comprising one or a combination of more than one compound selected from the group consisting of an adjuvant, one or more cytokines, antibodies against CD2, CD3, CD27, CD28, T cell surface antigens, or helper epitopes, classified in class 424, subclass 185.1.

Group 11. Claim 10, drawn to vaccines comprising nucleotide sequences encoding a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at position 2 *or* position 8 within said sequence is replaced with a substitute amino acid residue, and further comprising one or a combination of more than one compound selected from the group consisting of an adjuvant, one or more cytokines, antibodies against CD2, CD3, CD27, CD28, T cell surface antigens, or helper epitopes, classified in class 536, subclass 23.1 and class 424, subclass 184.1.

Group 12. Claim 10, drawn to vaccines comprising an antigen presenting cell preloaded with a peptide comprising at least part of the

amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue, and further comprising one or a combination of more than one compound selected from the group consisting of an adjuvant, one or more cytokines, antibodies against CD2, CD3, CD27, CD28, T cell surface antigens, or helper epitopes, classified class 424, subclass 93.1.

Group 13. Claim 10, drawn to vaccines comprising a T cell receptor against a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue, and further comprising one or a combination of more than one compound selected from the group consisting of an adjuvant, one or more cytokines, antibodies against CD2, CD3, CD27, CD28, T cell surface antigens, or helper epitopes, classified in class 530, subclass 350.

Group 14. Claim 10, drawn to vaccines comprising cells expressing a T cell receptor against a peptide comprising at least part of the amino acid sequence of SEQ ID NO:1, wherein the amino acid residue at either position 2 *or* position 8 within said sequence is replaced with a different amino acid residue, and further comprising one or a combination of more than one compound selected from the group consisting of an adjuvant, one or more cytokines, antibodies against CD2, CD3, CD27, CD28, T cell surface antigens, or helper epitopes, classified in class 424 , subclass 93.1.

6. The inventions listed as Groups 1-14 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-8 and 10-14 as disclosed include biologically and chemically distinct, unrelated in structure and function, made by and used in different methods, and are therefore distinct inventions.

Inventions 1 and 9 include materially different methods which differ at least in objectives, method steps, reagents, and/or dosages, and/or schedules used, response variables, and criteria for success, and are therefore distinct inventions.

The inventions of Groups 1 and 9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the peptide products as claimed can be used in a materially different process such as vaccination.

The inventions of Groups 2-8/10-15 and 1/9 are not at all related because the products of Groups 2-8/10-15 are not used in any of the method steps of Group 1/9.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated in proper.

Election/Species

8. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claim 10 of Groups 10-14 is drawn to vaccine further comprising one or more compounds. Each combination of one or more compounds is regarded as a distinct species. The species are as follows:

1. Vaccines further comprising an adjuvant.
2. Vaccines further comprising one or more cytokines.
3. Vaccines further comprising antibodies directed against CD2.
4. Vaccines further comprising antibodies directed against CD3.
5. Vaccines further comprising antibodies directed against CD27.
6. Vaccines further comprising antibodies directed against CD28.
7. Vaccines further comprising antibodies directed against other T cell surface antigens.
8. Vaccines further comprising antibodies directed against other helper epitopes.

9. Specifically elected vaccines further comprising any one combination of more than one of the compounds included in the Markush group of Claim 10.

9. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The products of the above species represent separate and distinct molecules or combinations of molecules with different structures and functions such that one species could not be interchanged with the other.

As such, each species would require different searches and the consideration of different patentability issues.

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. A telephone call was made to Barbara Rae-Venter on November 7, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Art Unit 1642

slr

November 20, 2000